DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

m4276n

WARNING LETTER

October 2, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-01

Facility ID: 180406

Russell Test
Chief Executive Officer/Radiology Administrator
The Hospital
43 Pearl Street
Sidney, NY 13838

Dear Mr. Test:

Your facility was inspected on September 26, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration. This inspection revealed serious regulatory problems involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

(1) Phantom QC records were missing for 12 weeks for the [redacted] unit #1.

(2) Phantom QC records were missing for 12 weeks for the [redacted] unit #2.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify failures to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with,

MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

There were also Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings were:

(1) Your facility has no written procedure for infection control.

(2) Mammograms were processed in your [redacted] processor when it was out of limits on three days, 3/14, 15 & 16/2000.

(3) The medical physicist's survey for x-ray unit #2, [redacted], is incomplete because it did not include an artifact evaluation.

(4) One of ten random reports reviewed did not contain an assessment category.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely yours,

Robert L. Hart
Acting District Director
New York District

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
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cc: Gerald O'Connor
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